Section 5. 510(k) Summary

SEP 27 2012

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Date Prepared
20 June 2012

Trade Name
Super Sheath Introducer Sheath and Super Sheath Introducer Sheath Set

Classification Name
Catheter Introducer

Regulation Number
870.1340

Product Code
DYB

Classification Panel
Cardiovascular

Device Class

Class II

Predicate Device

1. K052557: Super Sheath Introducer Sheath and Introducer Sheath Sets, 4F-9F

Togo Medikit Co., Ltd. previously submitted Special 510(k) K060190 Super Sheath XL Introducer Sheath to add sizes 10F, 11F, 12F and 14F to the range previously cleared under predicate device premarket notification number K052557. Special 510(k) K060190 was determined substantially equivalent on 04 April 2006 and added sizes 10F, 11F, 12F and 14F.

Indications for Use

The Super Sheath Introducer Sheaths and Super Sheath Introducer Sheath Sets are indicated for use in the introduction of diagnostic and interventional devices inserted into the human vasculature of adult and pediatric patients of all ages.

Device Description

The Super Sheath Introducer Sheaths and Super Sheath Introducer Sheath Sets are similar to the 4F-9F with the addition of the 3.3 French sheath, compatible dilator and guidewire to the sheath line. The Super Sheath Introducer Sheath is available in 3.3F and lengths of 5 cm and 7 cm. The device is provided sterile and intended for one procedure use only.

The Super Sheath Introducer Sheath is packaged with one dilator. The Super Sheath Introducer Sheath Set consists of one sheath, one dilator, and one guidewire with inserter. The sheath shaft and hub are manufactured of polyamide and ethylene tetrafluoro ethylene; one-piece construction of the sheath shaft and hub allows smooth passage of medical devices. The hub, color-coded by French size, contains a hemostatic valve to prevent blood leakage during a procedure. A side tube equipped with a three-way stopcock is attached to the sheath hub. The side tube extension may be used for fluid and medication administration, as well as blood sampling.

The dilator is an open, tapered plastic tube with an integral luer hub for guidewire insertion. The guidewire is inserted into the introducer sheath to facilitate and support entry of the sheath into the patient's vasculature. The dilator is longer than the sheath with a rounded tapered distal tip. The 3.3F Super Sheath Introducer Sheaths and provided dilator are compatible with a maximum recommended 0.025" guidewire. The dilator tubes are manufactured of polypropylene. Dilator tubes are press-fit into the dilator hub with a bushing. The sheath hub and dilator hub lock using a rotating motion.

Technological Characteristics and Substantial Equivalence

The following table compares the Super Sheath Introducer Sheaths and Super Sheath Introducer Sheath Sets to the predicate device with respect to intended use and technological characteristics, providing more detailed information regarding the basis for the determination of substantial equivalence.

Table 5-1. Device Comparison Table

Parameter	**Super Sheath (3.3F) Additional Size**	**Super Sheath (4F-9F) Predicate Device**
510(k)	To be assigned	K052557
Device Trade Name	Super Sheath Introducer Sheaths and Super Sheath Introducer Sheath Sets	Super Sheath Introducer Sheaths and Super Sheath Introducer Sheath Sets
Indications for Use	The Super Sheath Introducer Sheaths and Super Sheath Introducer Sheath Sets are indicated for use in the introduction of diagnostic and interventional devices inserted into the human vasculature of adult and pediatric patients of all ages.	Introducer Sheaths and Introducer Sheath Sets are intended for use in the introduction of diagnostic and interventional devices inserted into the human vasculature.
Regulation Number	870.1340	870.1310
FDA Product Code	DYB	DRE
Prescription / OTC Use	Prescription	Prescription
Single-Use / Reusable	Single-Use	Single-Use
Sheath		
French Sizes Available	3.3F	4F - 9F
Effective Length	5 cm – 7 cm (50 mm – 70 mm)	7 cm – 25 cm (70 mm – 250 mm)
Radiopaque Marker	Not applicable	Tantalum
Guidewire and Inserter		
Guidewire Tip Shape	Straight type	J-tip
Guidewire Recommended Maximum OD (Outer Diameter)	0.025"	0.035", 0.038"
Inserter	Available	Available
Sterilization and Shelf Life		
Sterilization Method	Ethylene oxide	Ethylene oxide
Sterile Package	Pouch	Pouch
Shelf Life (Use By Date)	Three (3) years	Three (3) years

Summary of Non-Clinical Data Submitted

Functional testing was conducted to verify the 3.3F Super Sheath Introducer Sheaths and Super Sheath Introducer Sheath Sets met product specification. Testing was conducted according to protocols based on international standards and in-house requirements, and included:

- Sheath Shaft Tensile Test
- Sheath Kink Test
- Connection Strength Test
- Hemostatic Valve Pressure Test
- Sheath Valve Integrity / Sheath Pressure Test
- Sheath Lubricity Test
- Sheath Radiopacity Test
- Sheath / Dilator Corrosion Resistance Test
- Dilator Tensile Test
- Dilator Connection Strength Test
- Guidewire Tensile Test
- Guidewire Radiopacity Test
- Guidewire Corrosion Resistance Test
- Guidewire Torque Load Test
- Guidewire Torqueability Test

Additionally the 3.3F Super Sheath Introducer Sheaths and Super Sheath Introducer Sheath Sets were adopted into the existing ethylene oxide sterilization cycle for sheath products, which was validated in accordance with ISO 11135-1:2007.

Biocompatibility, packaging and product shelf life testing was provided in K052557. The devices tested included materials and packaging used in the 3.3F Super Sheath Introducer Sheaths and Super Sheath Introducer Sheath Sets included in this Special 510(k) premarket notification. Additional testing was not conducted.

Safety and Effectiveness

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device, or has the same intended use and different technological characteristics, and it can be demonstrated that the device is substantially equivalent to the predicate device, and that the new device does not raise different questions regarding its safety and effectiveness as compared to the predicate device.

It has been shown in this 510(k) submission that the differences between the 3.3F Super Sheath Introducer Sheaths and Super Sheath Introducer Sheath Sets and predicate devices do not raise any questions regarding its safety and effectiveness. The 3.3F Super Sheath Introducer Sheaths

and Super Sheath Introducer Sheath Sets, as designed and manufactured, therefore are determined to be substantially equivalent to the referenced predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 27 2012

Togo Medikit Co., Ltd.
c/o Ms. Heather Crawford, RAC
Sr. Quality and Regulatory Consultant, Emergo Group
611 West 5th Street, Third Floor
Austin, TX 78701

Re: K121504
Trade/Device Name: Super Sheath Introducer Sheaths and Super Sheath Introducer Sheath Sets
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter, Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: August 14, 2012
Received: August 16, 2012

Dear Ms. Crawford:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

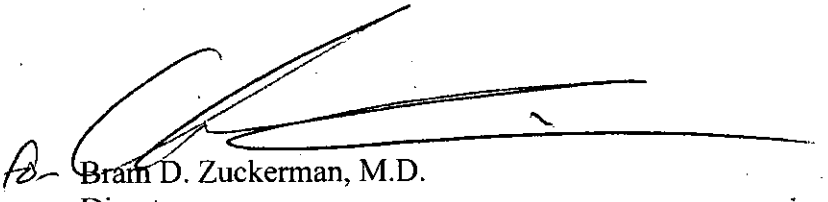
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Brain D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Super Sheath Introducer Sheaths and Super Sheath Introducer Sheath Sets

Indications for Use: The Super Sheath Introducer Sheaths and Super Sheath Introducer Sheath Sets are indicated for use in the introduction of diagnostic and interventional devices inserted into the human vasculature of adult and pediatric patients of all ages.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K 121509